



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket No. 006420.00004)

In re U.S. Patent Application of: )  
Dharmadhikari, et al. )  
Application No.: 10/526,285 ) Group Art Unit: 1614  
Filed: March 2, 2005 ) Confirmation No.:  
For: Pharmaceutical Composition of Metaxalone ) Examiner: Michel Graffeo  
with Enhanced Oral Bioavailability )

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.97 and 1.98, the Applicant wishes to make the following documents listed on the enclosed PTO/SB/08A&B of record in the above-identified application. Copies of the non-U.S. Patent documents are enclosed.

This Information Disclosure Statement is being submitted in compliance with 37 C.F.R. 1.56 as an Examiner might consider the cited documents important in deciding whether to allow the application to issue as a patent, but the citation of such documents is not to be construed as an admission that such documents are necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner in the normal course of examination, will make an independent search and will determine the best prior art, and in the course of such search, will review for relevance of the documents cited on the attached form even if not initialed.

The Commissioner is authorized to charge \$180.00 resulting from the filing of this IDS.

Respectfully submitted,

Dated: March 2, 2005

By:

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PTO/SB/08a (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet	1	of	2
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**Complete if Known**

<i>Application Number</i>	10/526,285
<i>Filing Date</i>	03/02/2005
<i>First Named Inventor</i>	Dharmadhikari, et al.
<i>Art Unit</i>	1614
<i>Examiner Name</i>	Michel Graffeo
<i>Attorney Docket Number</i>	006420.000004

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kind Codes and USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08b(08-03)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 2

**Complete if Known**

Application Number	10/526,285
Filing Date	03/02/2005
First Named Inventor	Dharmadhikari, et al.
Art Unit	1614
Examiner Name	Michel Graffeo
Attorney Docket Number	006420.00004

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	3	BRITTAİN, HARRY G., "Thermodynamics of Polymorphs", Polymorphism in Pharmaceutical Solids, 1999, pgs. 10-18, 290, Marcel Dekker, Inc., USA	
	4	LACHMAN, LEON, "Crystal Form", The Theory and Practice of Industrial Pharmacy, 1987, pg. 222, Varghese Publishing House, India	
	5	MARTIN, ALFRED, "Micromeritics", Physical Pharmacy, 1993, pgs. 426-429, B.I. Waverly Pvt Ltd.	
	6	U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Approved Drug Products with Therapeutic Equivalence Evaluations [online]. 26 <sup>th</sup> edition [retrieved 2006-3-1]. Retrieved from the Internet: <URL:http://www.fda.gov/cder/orange/obannual.pdf>, pgs. 3-241, 6-167, A-48, B-59, ADA 78	
	7	Skelaxin ® (Metaxalone), Revised August 2002, pgs. 3-6, Retrieved from the Internet: <URL:http://www.fda.gov/cder/foi/label/2002/13217s0361lbl.pdf>	
	8	U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations [retrieved 2006-3-1]. Retrieved from the Internet: <URL:http://www.fda.gov/cder/ob/docs/query>, 6 pages.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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